REMARKS

I. Status of the Claims

Upon entry of the amendments made herein, claims 1-14, 19-21, 24, 25, and 28-37 are pending in this application. Claims 15-18 were previously cancelled. Claims 1-14,19-21, 25, and 29 are amended herein. Independent claim 1 has been amended to recite that the marine oil is in a pharmaceutical composition, which is not a health supplement. Support for that amendment may be found in the specification on page 13, lines 5-24. Applicants have also amended dependent claims 2-14, 19-21, 25, and 29 for purposes of clarification. No new matter is added by any of the amendments herein.

Applicants have added independent claim 30 and dependent claims 31-37. Independent claim 30 is similar to original independent claim 1 but recites that the cholesterol concentration in the final product is 1.4 mg/g to 3 mg/g. Support for that limitation may be found at page 8 of the specification (stating that, typically, fish oils contain 3-6 mg/g free cholesterol, which concentration is reduced by the inventive process) and in Example 1 at page 22, lines 5-12 and Table 1, Test 1 (showing that the free cholesterol of a fish oil originally containing 6 mg/g was reduced to 1.4 mg/g).

Applicants thank the Office for allowing previously pending claims 1-14 and 19-21. Office Action at page 4.

II. Rejection under 35 U.S.C. § 102(b)

The Office rejects claims 22-29 under 35 U.S.C. § 102(b) as being "pseudo product-by-process claims." Office Action at page 2. Claims 24, 25, 28, and 29 dependent from claim 1. Claim 1 has been amended to recite that the marine oil is in a

pharmaceutical composition, which is not a health supplement. None of the cited art is drawn to a pharmaceutical composition, as presently claimed. Accordingly, Applicants respectfully request withdrawal of this rejection.

Furthermore, new claims 36 and 37 depend from claim 30. Independent claim 30 recites that the composition has a cholesterol concentration of 1.4 mg/g to 3 mg/g. None of the cited art is drawn to such a composition. Accordingly, Applicants respectfully request withdrawal of this rejection.

III. Allowability of Amended Claims 1-14, 19-21, 24, 25, and 28-37

Omacor® is a commercially available product supplied as a liquid-filled gel capsule for oral administration. Each one-gram capsule contains at least 900 mg of the ethyl esters of omega-3 fatty acids, approximately 840 mg of which are eicosapentaenoic acid (EDA) ethyl ester (approximately 465 mg) and docosahexaenoic acid (DHA) ethyl ester (approximately 375 mg). Omacor® is approved by the U.S. Food & Drug Administration (FDA) for use to reduce very high (≥ 500 mg/dL) triglyceride levels in adult patients, as an adjunct to diet. Applicants believe that claims 1-14, 19-21, and 30-35 read on a process that can be used to make Omacor®. And claims 24, 25, 28, 29, 36, and 37 read on Omacor® itself.

Omacor® was approved in the U.S. in November 2004, and was launched shortly thereafter. It was first registered in Norway in 1994. Omacor® was not sold or made in the U.S. before the invention of the present application. Applicants also submit herewith issued U.S. patents that read on Omacor®. For example, U.S. Patent Nos. 5,502,077, 5,656,667, and 5,698,594 are listed in the FDA's Orange Book for Omacor®.

Applicants also sold certain health supplements under the brandname "EPAX" in Europe. Certain of those health supplements were also sold in the U.S. prior to the priority date of the present application. However, no EPAX products were made in the U.S. prior to the priority date of the present application. Furthermore, unlike the process of making Omacor® and that product, the process of making EPAX products and EPAX products do not fall within the scope of the present claims at least because those products are health supplements, not pharmaceutical compositions, as presently claimed in claims 1-14, 19-21, 24, 25, 28, and 29.

Furthermore, the process of making EPAX products and the EPAX products do not fall within the scope of new claims 30-37 at least because those products did not comprise a marine oil comprising 1.4 mg/g to 3 mg/g of cholesterol in free form.

Accordingly, Applicants respectfully request the entry of the amendments contained herein and the timely allowance of claims 1-14, 19-21, 24-25, and 28-37.

If the Examiner has any questions regarding this amendment, she is invited to call the undersigned at 202-408-4105.

If there is any fee due in connection with the filing of this Amendment, please charge the fee to Deposit Account 06-0916.

Respectfully submitted,
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